



## Early Breast Cancer – PBS Authority Application

For PBS subsidised treatment of patients with HER2 positive early breast cancer

### Supporting information form

#### Instructions

This document contains the form you must lodge for a patient commencing PBS subsidised treatment with trastuzumab, for HER2 positive early breast cancer.

#### Patient acknowledgement form

TO BE SIGNED BY PATIENT AND THE PRESCRIBER IN THE PRESENCE OF A WITNESS (OVER 18 YEARS OF AGE) AND MUST BE SENT IN WITH THE APPLICATION.

#### Section 100 arrangements

This item is only available to a patient who is attending an approved private hospital or public participating hospital or public hospital and is a day admitted patient, a non-admitted patient or a patient on discharge. This is not a PBS benefit for inpatients of the hospital.

Hospital provider number must be included on this form.

#### Authority prescription form

A completed authority prescription form must be included with this document. The Early Breast Cancer PBS authority application supporting information form replaces the requirement to complete the medical indication section of the authority prescription form when submitted in accordance with the authority restriction.

No applications for increased repeats will be authorised.

#### In writing

All initial applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Patients who **have not** commenced treatment with trastuzumab:

An in-situ hybridisation (ISH) pathology report must be provided with the application.

Patients already commenced on non-PBS subsidised treatment with trastuzumab:

The date of commencement of treatment and the number of weeks treatment received must be provided with the application.

#### Phone approvals

Where less than the approved quantity has been requested at the time of the initial application, subsequent phone approvals may be granted to complete that treatment course. Applications for remaining treatment may be made by telephoning 1800 700 270 between 8am and 5pm EST Monday to Friday.

**Under no circumstances will telephone approvals be granted for complete initial authority applications.**

#### Applications for initial treatment

**Patients who have not commenced treatment or who were receiving chemotherapy following surgery at 1 October 2006:**

All applications for initial treatment will be limited to provide for a maximum of 3 weeks of therapy.

The medical practitioner should request sufficient quantity based on the weight of the patient as follows:

- For once weekly dosing, equivalent number of vials for the loading dose of 4mg/kg, and 2 weekly doses of 2mg/kg.
- For 3 weekly dosing, equivalent number of vials for one loading dose of 8mg/kg.

**Patients who have received non-PBS subsidised treatment with trastuzumab:**

Applications for initial PBS subsidised treatment will be limited to provide for a maximum of 3 weeks of therapy and up to a maximum of 3 repeats. The medical practitioner should request sufficient quantity based on the weight of the patient as follows:

- For once weekly dosing, the equivalent number of vials for 3 doses of 2mg/kg.
- For 3 weekly dosing, the equivalent number of vials for 1 dose of 6mg/kg.

#### Applications for continuing treatment

All applications for continuing treatment may be made by telephoning 1800 700 270 between 8am and 5pm EST Monday to Friday.

A maximum of 3 weeks therapy and up to a maximum of 3 repeats may be approved. The medical practitioner should request sufficient quantity based on the weight of the patient as follows:

- For once weekly dosing, the equivalent number of vials for 3 doses of 2mg/kg.
- For 3 weekly dosing, the equivalent number of vials for 1 dose of 6mg/kg.

#### Lodgement

Please send the completed authority supporting information form and authority prescription form with all relevant attachments to:

Medicare Australia  
Prior written approval of specialised drugs  
Reply paid 9826  
GPO Box 9826  
Hobart TAS 7001

The information on this form is correct at the time of publishing and is subject to change. Please check Medicare Australia website



## Dosage Charts for Weekly and 3 Weekly Dosing Regimes

Once weekly dosing – *Three weeks* therapy approved at each application

New patient (i.e. loading dose) or repeat loading (1 x loading dose [4mg/kg] + 2 x continuing doses [2mg/kg])	
Patient weight	No. of vials for 3 weeks treatment
Up to 38 kg	3
38-75kg	4
76 - 112kg	7
113-150kg	8
151-187kg	11

Continuing applications 2mg/kg (3 x continuing doses) + Max 3 Rpts	
Patient weight	No. of vials for 3 Weeks treatment
Up to 75kg	3
76 - 150kg	6
> 150kg	9

Three weekly dosing – *Three weeks* therapy approved at each application

New patient (i.e. loading dose) 8mg/kg (1 x loading dose)	
Patient weight	No. of vials for 3 weeks treatment
Up to 37kg	2
38 - 56kg	3
57 - 75kg	4
76 - 93kg	5
94 - 112kg	6
113 - 131kg	7
132 - 150kg	8
Greater than 150kg	9

Continuing applications 6mg/kg (1 x continuing dose) + Max 3 Rpts	
Patient weight	No. of vials for 3 weeks treatment
Up to 50kg	2
51 - 75kg	3
76 - 100kg	4
101 - 125kg	5
126 - 150kg	6
Greater than 150kg	7



# Early Breast Cancer – PBS Authority Application

For PBS subsidised treatment of patients with HER2 positive early breast cancer

## Supporting information form Patient acknowledgement form

Please read this acknowledgement carefully.

Print neatly in BLOCK LETTERS.

This form must be signed by the patient and the prescriber in the presence of a witness (over 18 years of age). The completed acknowledgement form must be sent to Medicare Australia with the PBS authority application supporting form for early breast cancer.

### Patient's declaration

I understand and acknowledge that Pharmaceutical Benefits Scheme (PBS) subsidised treatment with trastuzumab for HER2 positive early breast cancer will cease:

- when I have received a total of 52 weeks treatment which includes, where applicable, any non-PBS subsidised treatment; OR
- if my cardiac function demonstrates I have a left ventricular ejection fraction (LVEF) of < 45% and/or symptomatic heart failure.

### Patient details

Family name

First name

Date of birth

Medicare/DVA number

Signature of patient

### Prescriber's declaration

I have explained the circumstances and test requirements governing the supply of PBS subsidised treatment with trastuzumab for HER2 positive early breast cancer. To the best of my knowledge I believe these to be understood and accepted by the patient.

Signature of prescriber

Prescriber's name

### Witness

I have witnessed the signature of **BOTH** the patient and the prescriber.

Signature of witness (over 18 years of age)

Witness's name  Date

**Privacy note:** The information on this form will be used to assess applications and eligibility for the nominated patient under the restrictions for PBS subsidised treatment with trastuzumab for early breast cancer. The collection of this information is authorised under provisions of the *National Health Act 1953* and may be disclosed to the Department of Health and Ageing, the Department of Human Services, or as authorised or required by law.



# Early Breast Cancer – PBS Authority Application

For PBS subsidised treatment of patients with HER2 positive early breast cancer

## Supporting information form

**Initial PBS subsidised treatment with trastuzumab of patients with HER2 positive early breast cancer. This form must be completed by the treating prescriber.**

If you need assistance please call 1800 700 270.

Please complete all parts of this application form. Please print neatly in BLOCK LETTERS.

### Part 1—Patient details

Medicare/DVA number

Family name

First name

Date of birth  /  /  Patient's current weight  kg

### Part 2—Conditions and criteria

#### Eligibility

To qualify for PBS authority under this criterion your patient must meet the following conditions:

**Please indicate the patient's eligibility by ticking:**

The patient named above

has early breast cancer;

**AND**

has had cardiac function tested by a suitable method and does not have a left ventricular ejection fraction (LVEF) of <45% and/or symptomatic heart failure;

**AND**

has signed and supplied a patient acknowledgement form with this application.

For patients who have undergone surgery and who wish to commence trastuzumab concurrently with adjuvant chemotherapy, please complete **Part 3**.

For patients who were receiving adjuvant chemotherapy following surgery at 1 October 2006, please complete **Part 4**.

For patients receiving non-PBS subsidised treatment with trastuzumab for early breast cancer at 1 October 2006, please complete **Part 5**.

### Part 3—Patients with no prior treatment

The patient named above:

is HER2 positive as demonstrated by in-situ hybridisation (ISH) [pathology report attached]

**AND**

has undergone surgery

**AND**

is to commence trastuzumab while receiving adjuvant chemotherapy

Please indicate dosage regime:  Once weekly  3 weekly

Please attach a prescription to provide for a maximum of 3 weeks treatment as per dosage chart on Page 2.

Please go to Part 6

#### Part 4—Patients receiving chemotherapy at 1 October 2006

The patient named above:

is HER2 positive as demonstrated by in-situ hybridisation (ISH) [pathology report attached]

AND

has undergone surgery

AND

was receiving adjuvant chemotherapy following surgery at 1 October 2006

Please indicate dosage regime:  Once weekly  3 weekly

Please attach a prescription to provide for a maximum of 3 weeks treatment as per dosage chart on Page 2.

Please go to Part 6

#### Part 5—Patients receiving non-PBS subsidised treatment with trastuzumab for early breast cancer at 1 October 2006

The patient named above:

is HER2 positive

AND

Commenced treatment with trastuzumab on

AND

Has received a total of  weeks treatment

Please indicate dosage regime:  Once weekly  3 weekly

Please attach a prescription to provide for a maximum of 3 weeks treatment as per dosage chart on Page 2 and up to a maximum of 3 repeats.

Please go to Part 6

#### Part 6—Prescriber details

Prescriber number

Phone number  Fax number

Prescriber name  Hospital Name

Prescriber signature  Hospital Provider Number

Date

#### Part 7—Lodgement

Please send the completed authority application form and authority prescription form with all relevant attachments to:

Medicare Australia

Prior written approval of specialised drugs

Reply paid 9826

GPO Box 9826

Hobart TAS 7001

**Privacy note:** The information on this form will be used to assess applications and eligibility for the patient under the restrictions for PBS subsidised treatment with trastuzumab for early breast cancer. The collection of this information is authorised under provisions of the *National Health Act 1953* and may be disclosed to the Department of Health and Ageing, the Department of Human Services, or as authorised or required by law.